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# Medical countermeasures for national security: A new government role in the pharmaceuticalization of society

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## ABSTRACT

How do governments contribute to the pharmaceuticalization of society? Whilst the pivotal role of industry is extensively documented, this article shows that governments too are accelerating, intensifying and opening up new trajectories of pharmaceuticalization in society. Governments are becoming more deeply invested in pharmaceuticals because their national security strategies now aspire to defend populations against health-based threats like bioterrorism and pandemics. To counter those threats, governments are acquiring and stockpiling a panoply of 'medical countermeasures' such as antivirals, next-generation vaccines, antibiotics and anti-toxins. More than that, governments are actively incentivizing the development of many new medical countermeasures – principally by marshaling the state's unique powers to introduce exceptional measures in the name of protecting national security. At least five extraordinary policy interventions have been introduced by governments with the aim of stimulating the commercial development of novel medical countermeasures: (1) allocating earmarked public funds, (2) granting comprehensive legal protections to pharmaceutical companies against injury compensation claims, (3) introducing bespoke pathways for regulatory approval, (4) instantiating extraordinary emergency use procedures allowing for the use of unapproved medicines, and (5) designing innovative logistical distribution systems for mass drug administration outside of clinical settings. Those combined efforts, the article argues, are spawning a new, government-led and quite exceptional medical countermeasure regime operating beyond the conventional boundaries of pharmaceutical development and regulation. In the first comprehensive analysis of the pharmaceuticalization dynamics at play in national security policy, this article unearths the detailed array of policy interventions through which governments too are becoming more deeply imbricated in the pharmaceuticalization of society.

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## 1. Introduction

Recent scholarship identifies multiple drivers for the pharmaceuticalization of society (Abraham, 2010; Gabe, 2014; Williams et al., 2009, 2011). Scientific advances in biomedicine are one significant factor, because such discoveries enable novel pharmaceutical products to be developed (Clarke et al., 2010). The broader medicalization of existence too is a relevant driver, as it encourages a social tendency to address complex issues through recourse to pharmaceutical therapies (Conrad, 2007). More aggressive industry promotion and direct-to-consumer advertising can similarly increase the societal penetration of pharmaceutical products, which is why several influential studies have emphasized the influence of

pharmaceutical companies (Healy, 1997, 2004; Dumit, 2012; Goldacre, 2012). Governments by contrast have so far only been accorded a much more modest role in the scholarship, which tends to focus on the expedited approaches some state regulatory agencies are taking in the approval of new pharmaceuticals (Abraham, 2010; Williams et al., 2011). This article, however, shows that governments are much more active and complex drivers of pharmaceuticalization than the received picture suggests. Governments too are today accelerating, intensifying and opening up new trajectories of pharmaceuticalization in society; and they are doing so through a much broader array of policy instruments than just their regulatory powers alone.

Key to this renewed political investment in pharmaceuticals is the fact that governments now view the protection of their populations against acute infectious disease threats as a core part of their national security mission. The World Health Organization (WHO) has warned governments that a new pandemic infecting

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roughly 25% of the world population (a figure derived from previous pandemics), would affect more than 1.5 billion people and cause enormous social disruption due to a rapid surge in illnesses and deaths (WHO, 2007: 47). Governments have also been spurred into preparing for the deliberate release of a biological agent through an act of bioterrorism – as exemplified by the anthrax letters mailed in the United States in the autumn of 2001. Acknowledging those microbial vulnerabilities, governments in the United States and Europe have expanded their security agendas to formally incorporate health-based threats (WHO, 2007; EC, 2009). Indeed, the rapid proliferation of the new notion of ‘health security’ in a plethora of international policy debates and official documents testifies to the growing significance that governments now attach to defending their societies against such infectious disease threats (WHA, 2001; GHSI, 2002; WHO, 2007; European Council, 2008; EC, 2009; Elbe, 2009, 2010b). Security policy, as Melinda Cooper observes, needs ‘to arm itself against the generic microbiological threat, from wherever it might emerge’ (Cooper, 2008:75).

One of the principal ways governments are trying to counter those threats is by acquiring and stockpiling a panoply of ‘medical countermeasures’ – like antivirals, next-generation vaccines, antibiotics and anti-toxins. So strong, in fact, is the political interest in obtaining better pharmaceutical defences, that governments are also trying to actively incentivize the commercial development of many new medical countermeasures. This article identifies, maps and analyzes the complex array of new policy initiatives governments are introducing to stimulate the development of such novel medical countermeasure. For its source material, the article draws upon semi-structured, background interviews carried out with key informants from government, industry and academia in the United States and Europe, where medical countermeasures are a political priority. Informants were selected on the basis on their detailed knowledge of the government programmes and regulatory procedures surrounding medical countermeasures. Interviews explored the key issues involved in the development, approval, and deployment of medical countermeasures – especially of antivirals and vaccines. Those findings were corroborated through extensive analysis of a wide range of policy papers, background papers, working papers and articles on medical countermeasures produced by governments, think tanks, and newspapers; as well as of scholarly articles and books published on health security.

Analysis of the source material suggests that recent government efforts to stimulate the commercial development of new medical countermeasures principally rely upon the state’s unique power to introduce exceptional measures in the name of protecting national security. At least five extraordinary government interventions can be identified: (1) allocating earmarked public funds, (2) granting comprehensive legal protections to pharmaceutical companies against injury compensation claims, (3) introducing bespoke pathways for regulatory approval, (4) instantiating emergency use procedures, and (5) designing innovative logistical distribution systems for mass drug administration beyond clinical settings. Those combined measures are spawning a new, government-led and quite exceptional medical countermeasure regime operating outside of the conventional boundaries of pharmaceutical development and regulation. In the first comprehensive analysis of the pharmaceuticalization dynamics at play in contemporary security policy, this article unearths the array of policy interventions through which governments are becoming more deeply imbricated in the pharmaceuticalization of society.

## 2. Health security: the microbial turn in security policy

The ‘biological’ – even ‘microbial’ – turn in security policy is increasingly well documented (Cooper, 2008; Elbe, 2003, 2009,

2010b; Lakoff and Collier, 2008; McInnes and Lee, 2006; Enemark, 2009; Rushton and Youde, 2014). Scholars in International Relations have advanced detailed explorations of how a number of pressing international health issues have become ‘securitized’ (Elbe, 2006, 2010a; Davies, 2008; McInnes and Rushton, 2013). Scholars of public health, conversely, have documented how that field is simultaneously becoming more security oriented – reminding readers of the historical legacies of linking public health and security in the context of colonialism (King, 2002, 2003; Brown, 2011; Brown and Bell, 2008; Wright, 2006). Irrespective of whether one starts from the perspective of security or public health, it is evident that the worlds of security and health are beginning to converge ever more closely – conceptually, institutionally, and programmatically.

Two distinct but related infectious disease threats animate this convergence. The first threat – bioterrorism – surfaced in security debates during the 1990s. The subsequent terrorist attacks of 11 September 2001 in the United States, and the mailing of letters laced with Anthrax through the U.S. postal system, would prove decisive in elevating political perceptions about bioterrorism. As David Franz, the former Commander of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), put it in 2002:

The thought of an outbreak of disease caused by the intentional release of a pathogen or toxin in an American city was alien just 10 years ago. Many people believed that biological warfare was only in the military’s imagination, perhaps to be faced by soldiers on a far-away battlefield, if at all. The “anthrax letters” and the resulting deaths from inhalation anthrax have changed that perception. The national, state, and local governments in the United States are preparing for what is now called “not if, but when and how extensive” biological terrorism (Franz and Zajtcuk, 2002).

The threat of a *deliberate* release of a disease-causing agent thus marks one key driver for increased national security concerns about acute infectious diseases.

Slightly different drivers are at play in the case of *naturally* occurring infectious diseases – like pandemic influenza (Dry and Leach, 2010; Dingwall et al., 2013; Figuié, 2013). Many public health experts observe that three such flu pandemics occurred in the twentieth-century alone (Kilbourne, 2006). First came the pandemic of 1918, undoubtedly the worst of the twentieth-century when measured by scale of absolute human mortality. It struck at the end of the First World War, and therefore prior to the widespread availability of antibiotics and respirators – contributing to a severe mortality rate estimated to run into the tens of millions (Johnson and Mueller, 2002). Two further pandemics (in 1957 and 1968) followed in the second half of the twentieth century, albeit with considerably smaller death tolls. The cyclical periodicity of these events has nonetheless generated a perception amongst public health experts that future pandemics are inevitable. As Angus Nicoll, head of the influenza programme at the European Centre for Disease Prevention and Control (ECDC) puts it: ‘European policy-makers and politicians are put in a hard place by the prospect of modern influenza pandemics. They don’t know when one is going to happen, where it will start or what it will be like. The only certainty is that future influenza pandemics will occur and they will be unpredictable’ (Nicoll and Sprenger, 2011).

Both of those ‘twin’ infectious disease threats have been subject to diverging expert assessments regarding their likelihood and severity. Charles Allen, the Chief Intelligence Officer of the Department of Homeland Security, for example, testified before Congress that ‘in general, terrorist capabilities in the area of

bioterrorism are crude and relatively unsophisticated, and we do not see any indication of a rapid evolution of capability' (cited in Klotz, 2008: 109). Following the comparatively 'mild' pandemic of 2009, moreover, there has also been extensive public debate about the assumptions underpinning recent pandemic preparedness planning. Those uncertainties notwithstanding, the dual threats of bioterrorism and pandemics have already proved sufficiently potent politically over the past decade to prompt a progressive widening of security agendas.

Especially in the United States and Europe, national security policy now routinely includes the strengthening of 'health security'. In January 2000, for example, the US National Intelligence Council declassified an influential National Intelligence Estimate entitled *The Global Infectious Disease Threat and Its Implications for the United States*. The findings of the report showed that since 1973 at least 30 previously unknown disease agents have been identified (including some for which there is no cure such as HIV, Ebola, Hepatitis C, and Nipah virus). According to the report, 'new and reemerging infectious diseases will pose a rising global health threat and will complicate US and global security over the next 20 years' (NIC, 2000). The report marked a crucial turning point for introducing health issues onto the security agenda of the United States.

Soon other countries also became more concerned about health-based threats. Following the Anthrax letters of 2001, the health ministers of Canada, France, Germany, Italy, Japan, the United Kingdom, the United States, and Mexico met in Ottawa on 7 November 2001 to convene the first meeting of the new Global Health Security Initiative (GHSI). Devoted initially to countering the threat of bioterrorism, GHSI rapidly evolved to manage pandemic threats as well. That same year, the European Union created a new and high-level (albeit informal) Health Security Committee (HSC) in order to strengthen health security in the European Union (Kittelsen, 2013). Those on-going initiatives represent some of the most prominent institutionalizations of the idea of health security to date, which WHO has since defined as 'the activities required, both proactive and reactive, to minimize vulnerability to acute public health events that endanger the collective health of populations living across geographical regions and international boundaries' (WHO, 2007: ix).

Over time, such emerging concerns about health security also began to penetrate the formal national security strategies of several governments (Elbe, 2009, 2010; Weir and Mykhalovskiy, 2010). In the United States, for example, the National Security Strategy of 2002 stated that the government 'will also continue to lead the world in efforts to reduce the terrible toll of HIV/AIDS and other infectious diseases' (White House, 2002). The 2006 US National Security Strategy again directly acknowledged the threat posed by 'public health challenges like pandemics (HIV/AIDS, avian influenza) that recognize no borders' (NSS, 2006). When the United Kingdom developed its first formal national security strategy in 2008, pandemic threats were explicitly incorporated – both because of their ability to directly affect the country, and because they could potentially undermine international stability more generally (Cabinet Office, 2008: 3). Pandemic threats also continue to reside at the top of the UK national risk register and are identified as a (top) Tier 1 threat in the 2010 National Security Strategy (Cabinet Office, 2010: 27). Most recently, pandemic threats were similarly flagged up in France's 2013 Whitepaper setting out French national security policy for the period 2014–2019 (Livre Blanc, 2013; Kittelsen, 2013: 7). As we will see below, that expansion of national security agendas to formally include health-based threats has intensified government interest in acquiring pharmaceutical defences for their populations, and has allowed pharmaceutical logics to play a much more wide-ranging role in contemporary security policy.

### 3. Medical countermeasures: the rise of exceptional pharmaceuticals

When it comes to protecting their populations against health security threats, governments are turning towards pharmaceuticals as their preferred 'weapon' of choice. Nothing reflects this pharmaceutical turn in security policy more poignantly than the new category of 'medical countermeasures', which has been forged by governments to designate precisely those key pharmaceuticals that could also contribute to protecting national security. Examples of such medical countermeasures include antivirals, next-generation vaccines, antibiotics and anti-toxins (Hoyt, 2014; Elbe, 2014). Following a high-level workshop, the influential Institute of Medicine (IOM) in the United States defined medical countermeasures as 'a drug, biological product, or device that treats, identifies, or prevents harm from a biological, chemical, radiological, or nuclear agent that may cause a public health emergency' (IOM, 2010: 5).

That definition complements the U.S. government's aspiration to make pharmaceutical defences more widely available to the civilian population through the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). Citing the need to defend American citizens (rather than just the armed forces) against health security threats, PHEMCE takes the lead in 'protecting the civilian population from potential adverse health impacts through the use of medical countermeasures, which are medicines, devices, or other medical interventions that can lessen the harmful effects of these threats' (PHE, 2012). In a single concept, the notion of medical countermeasures thus captures how security policy is gravitating more closely towards pharmaceutical solutions, how health and security concerns increasingly interpenetrate each other, and how security planners are broadening out those pharmaceutical protections to cover entire populations. The very constitution of this new category of 'medical countermeasures' thus betrays the extent to which pharmaceuticals with the potential to strengthening health security have recently become a source of intensified political interest.

That pharmaceutical turn in security policy is evidenced further by the many sizeable pharmaceutical stockpiles governments have newly built in recent years. In 1999, and against the background of growing concerns about bioterrorism and large-scale natural disasters, the US Congress tasked the federal government with creating a new National Pharmaceutical Stockpile (NPS). In the event of an emergency, the NPS would supply states and communities with large quantities of essential medical material within 12 h of a government decision (Prior, 2004). Initially supported with an allocation of US\$ 51 million, the new stockpile was renamed the Strategic National Stockpile (SNS) in 2003, as it evolved into a much wider 'national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration and airway maintenance supplies, and medical/surgical items' (IOM, 2010: 6). By 2006, the push packages contained in the SNS occupied 124 cargo containers, weighed 94,424 pounds and required 5000 square feet of floor space (Prior, 2004: 7). Two years later, by 2008, the entire inventory of the stockpile was valued at US\$ 3.5 billion (Piester, 2008). This new pharmaceutical stockpile, the precise location and detailed composition of which remains classified, was first deployed following the terrorist attacks on 11 September 2001 in the United States (Prior, 2004: 2).

Although the United States government remains at the forefront of pharmaceutical stockpiling for national security purposes, the practice has also been adopted much more widely around the world – especially amongst other high-income countries with the requisite resources to do so. Prominent examples include the Australian government, which created a National Medical Stockpile (NMS) with a strategic reserve of essential vaccines, antibiotics and



antiviral drugs, and chemical and radiological antidotes, and personal protective equipment. The Canadian government similarly maintains a National Emergency Stockpile System (NESS). The United Kingdom too has established a Reserve National Stock for Major Incidents that includes nerve agent antidotes, antitoxins, antibiotics and other post-exposure medications – albeit on a smaller scale than the United States (MOD, 2010).

Within the context of pandemic preparedness planning, moreover, the UK government also created one of the world's largest stockpiles of antiviral medications. Amidst fears of an imminent H5N1 human flu pandemic in 2005, the UK government identified the antiviral medication *oseltamivir* (brand name: *Tamiflu*) as the 'first line of defence', and expended considerable public resources to create a stockpile of the drug sufficiently to cover half of the UK population. Subsequently the UK government increased the size of its antiviral stockpile further to cover eighty per cent of its population – effectively creating one of the world's largest antiviral stockpiles when measured by percentage of the population covered.

Many other governments around the world built similar antiviral stockpiles. A review of European pandemic plans focussing on 2005 found that by that time 20 European countries had already developed an antiviral-drug strategy – a trend that would continue to intensify (Mounier-Jack and Coker, 2006: 1408). By 2007, countries like France, Austria, Ireland, Luxemburg, and Switzerland had set antiviral stockpiling targets in excess of thirty percent of the civilian population, whilst countries like the Netherlands, Belgium, Hong Kong, the United States, Slovenia, the United Kingdom, Malta, Spain, Portugal, Finland and Sweden set them in excess of twenty percent (Trakatellis, 2007: 23; see also Mounier-Jack et al., 2007). Pharmaceutical stockpiling of medical countermeasures for civilian use has thus become a much more widespread government practice, and is certainly not one confined to the United States alone.

In fact, that trend towards large-scale antiviral stockpiling continued apace so that by 2009 a total of 95 governments around the world had reportedly purchased or ordered *Tamiflu* stockpiles. All in all, the manufacturer Roche has announced, around 350 million treatment courses [3.5 billion doses] were supplied to governments worldwide between 2004 and 2009 (Reddy, 2010: ii35). The political decisions to create those numerous new pharmaceutical stockpiles show that governments now widely believe the security of their populations to require more than just the traditional investments in armed force and the military, nuclear deterrence and so forth. What is arguably a government's highest political priority – ensuring national security – also demands a state capability to develop, acquire and rapidly orchestrate population-wide interventions with key medical countermeasures. Pharmaceuticals are becoming pivotal to national security.

#### 4. An extraordinary medical countermeasure regime

So strong is the government interest in pharmaceutical responses that officials are also trying to actively encourage the development of many *new* medical countermeasures. Proactive measures are deemed necessary because most research-based pharmaceutical companies – especially the sizeable, multinational ones – do not view medical countermeasures as a commercially attractive area. From a business point of view, the field is characterized by an uncertain regulatory environment, and a comparatively small market which usually only has one potential buyer – the government. By and large, pharmaceutical companies have thus determined medical countermeasures to be a high-risk, low-reward market, and have preferred directing their research capacities towards commercially more rewarding diseases. If governments want to see the rapid development of new medical

countermeasures to strengthen national security, they will have to create stronger incentives to stimulate a market response from commercial developers.

To overcome that challenge, governments have begun to spawn a whole new pharmaceutical regime aimed at enhancing the incentives for commercial medical countermeasure development. Drawing upon (but also adapting) the influential definition of regimes prevalent in International Relations (see Krasner, 1983), that medical countermeasure regime can be defined as the assemblage of implicit and explicit principles, norms, rules, institutions, and decision-making procedures converging around the development, approval, and use of pharmaceuticals in the area of health security. Governments have been able to create this new medical countermeasure regime by marshaling the state's power to introduce exceptional measures for the protection national security. Given the centrality of security to the maintenance of social, political and economic order, governments have the power to do things in the name of security that would otherwise be politically impossible. As the controversial legal theorist Carl Schmitt famously argued in *Political Theology*, 'sovereign is he who decides the exception'. Schmitt had thought that any legal order ultimately rests upon a political sovereign who has to take the decision when to suspend the normal legal system so as to secure the order as a whole. Under exceptional circumstances, it would be necessary to suspend the normal juridical order in the name of protecting security (e.g. declare a state of emergency).

Precisely this political power to determine the 'exception' also lies at the heart of the new pharmaceutical regime that governments have spawned for incentivizing new medical countermeasure development. With the rise of health-based threats like bioterrorism and pandemics, governments have effectively determined that some pharmaceuticals are 'exceptional' because they can contribute to the protection of national security, and have given them a special designation as 'medical countermeasures'. Once those medical countermeasures were conceptually differentiated from more routine pharmaceuticals, it then became possible for governments to adapt and suspend some of the normal processes surrounding pharmaceutical development, and – in the name of security – to introduce a new set of bespoke rules specifically governing the development of novel medical countermeasures.

As we will see in more detail below, at least five such extraordinary policy interventions can be identified. First, governments have intervened in the play of 'normal' market forces by creating an artificial and government-backed market in medical countermeasures underpinned by significant public funds. Second, governments exempted manufacturers of medical countermeasures from the usual legal compensation claims that might otherwise arise under tort law. Third, governments introduced bespoke pathways for the regulatory approval of medical countermeasures, enabling the use of animal studies. Fourth, governments introduced emergency use procedures that – in exceptional circumstances – would even allow for the use of unapproved medical countermeasures. Finally, governments also designed innovative logistical distribution systems for mass drug administration outside of routine clinical settings. In the name of national security, governments have engendered a new, government-led and quite exceptional medical countermeasure regime operating beyond the conventional boundaries of pharmaceutical development and regulation.

##### 4.1. Project BioShield: public funds for medical countermeasures

In order to lure companies into the area of countermeasures, governments started by intervening in the normal play of free

market forces. Drawing upon their power of taxation, some governments committed funds from the public purse to effectively constitute a new and government-backed market in medical countermeasures. Undoubtedly the most prominent example of such a government attempt to financially stimulate the commercial development of novel medical countermeasures is the Bioshield program launched in the United States in 2004. The legislation aimed to accelerate the research, development, purchase, and availability of new medical countermeasures by establishing a secure source of public funding worth US\$ 5.6 billion so that newly developed medical countermeasures could be bulk purchased by the US government (IOM, 2010: 6). Here, governments have sought to ‘artificially’ accelerate the development of new pharmaceutical products through creating additional financial incentives underpinned by public funds. That idea has subsequently also been popularised in other areas of international health policy, as seen in the use of advance market commitments to also stimulate the development of vaccines for rare and neglected diseases (Berndt et al., 2007).

Notwithstanding this substantial investment of public funds, it quickly became clear that financial incentives alone would be insufficient for luring a large number of commercially operating companies into the medical countermeasure market. In response to low commercial uptake, the US federal government decided in 2006 to go one step further by committing additional funds to establish a whole new organization dedicated to working more closely with commercial developers of new medical countermeasures – the Biomedical Advanced Research and Development Authority (BARDA). BARDA’s explicit mission is to develop and procure needed medical countermeasures – including vaccines, therapeutics, diagnostics, and also non-pharmaceutical countermeasures – against a broad array of public health threats, whether natural or intentional in origin. The organization’s primary strategic goals thus consist of creating an ‘advanced development pipeline replete with medical countermeasures and platforms to address unmet public health needs, emphasizing innovation, flexibility, multi-purpose and broad spectrum application, and long-term sustainability’ (BARDA, 2011).

Since its inception BARDA has rapidly emerged as one of the world’s most advanced medical countermeasure enterprises. BARDA has already initiated and/or completed acquisition contracts for medical countermeasures worth more than US\$ 2 billion – on anthrax antitoxins and vaccines, botulism therapeutics, smallpox vaccine, and radiological, nuclear and chemical threats (HHS, 2012). Overall, those contracts have culminated in the federal acquisition of tens of millions of doses of medical countermeasures (HHS, 2012). Under Project BioShield, the US government has so far been able to add eleven new products to the nation’s emergency stockpile; and – according to the Assistant Secretary for Preparedness and Response Nicole Lurie – there are another eighty pharmaceuticals in various stages of development for treating victims of a biological, chemical, nuclear or radiological incident (Schneidmiller, 2013). That comes against a background of a wider US government investment of more than US\$ 60 billion in civilian biodefense made available over the past decade, and in addition to any classified research conducted in the security and defence agencies (Franco and Sell, 2011: 119).

In Europe such initiatives to develop new medical countermeasures are still largely conducted at the level of national governments – with considerable disparities in terms of the political will and capabilities of countries to undertake such programmes. In the United Kingdom, for example, the Defence Science & Technology Laboratory (DSTL) – located within the Ministry of Defense – similarly initiated a medical countermeasures programme to develop a range of new pharmaceutical products for protecting the

UK population. What is more, when it comes to the mass procurement (rather than the development) of medical countermeasures for stockpiling purposes, greater degrees of co-operation are also beginning to emerge at the European level. A recent agreement reached on health security in the European Union, for example, established the legal basis for the voluntary joint procurement of medical countermeasures, especially of vaccines (EU, 2013). In the name of security, and in drawing upon their powers of taxation, some governments have taken the extraordinary step of intervening in the play of ‘normal’ market forces by making significant amounts of public funding available for incentivizing the commercial development and procurement of new medical countermeasures.

#### 4.2. The PREP Act: new legal protections for pharmaceutical companies

Although the provision of earmarked public funding is one key pillar of the government-led medical countermeasure regime, it is far from the only one. Governments have further incentivized the commercial development of new medical countermeasure by granting their manufacturers special and wide-ranging protections against lawsuits. These quite extraordinary protections are against legal compensation claims that could be reasonably anticipated to surface in the context of the mass administration of a new medical countermeasure – especially if unexpected side effects emerge. In the United States, a precedent for such protections was introduced through the National Childhood Vaccine Injury Act (NCVIA) of 1986, which focused on financial liabilities of vaccine manufacturers from injury claims. In 2005, and in the name of strengthening national security, such protections were extended to medical countermeasures more generally through the *Public Readiness and Emergency Preparedness Act* (PREP Act).

The PREP Act provides the Secretary of the Department of Health and Human Services with the power to issue a declaration providing immunity from tort liability – the area of law where a person who suffers an injury might sue to receive compensation from those responsible for causing the damage or injury. The provisions are principally intended to cover claims related to the administration of medical countermeasures during an emergency. The mechanism protects a wide range of ‘entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures’ (IOM, 2010: 6). The extensive types of loss covered by the PREP Act span: death; physical, mental, or emotional injury, illness, disability, or condition; and loss or damage to property (IOM, 2010: 22). That protection from tort liability is not completely unlimited, however, in that the act does not provide protections for death or serious injury arising from *willful* misconduct (IOM, 2010: 22).

This new mechanism has already been invoked on several occasions – in relation to acute radiation syndrome, to anthrax botulism, to pandemic influenza, to 2009 H1N1 influenza, and to smallpox. The medical countermeasures covered by these declarations to date include vaccines, antivirals (both *Tamiflu* and *Relenza*), and also respiratory devices (IOM, 2010: 24). Taking the extraordinary step of shielding commercial manufacturers from the financial risks associated with potential legal liabilities arising from the widespread use of medical countermeasures thus forms a second key mechanism through which governments are deploying the extraordinary powers of the state to incentivize the commercial development of new medical countermeasures. Governments are deploying not just their control of the public purse, but also their powers to suspend elements of the law in the name of protecting national security.

#### 4.3. The animal efficacy rule: special pathways for regulatory approval

The design of bespoke new pathways for the regulatory approval of medical countermeasures marks yet another extraordinary policy mechanism introduced by governments. A significant hurdle in developing new medical countermeasures is that it can be much more difficult to conduct the human clinical trials necessary for securing regulatory approval. Many of the diseases that could potentially be used for bioterrorism are not naturally occurring, or occur only in such small numbers that it is not feasible to run large clinical trials. There would also be strong ethical concerns about deliberately infecting humans with such agents in order to evaluate the effectiveness of new medicines. Commercial developers of medical countermeasures thus face the difficult question of how to obtain regulatory approval for their new products. Even where they may be able to do so, the mere existence of this additional regulatory complication generates increased commercial risk as to whether any product they are able to develop would ever secure the regulatory approval required for bringing it to market.

To diminish this regulatory 'disincentive', the US Food and Drug Administration (FDA) introduced a new 'animal rule' procedure in May 2002, which underwent a process of further review and public consultation in 2009 and 2010. The new rule deviates from the usual processes of regulatory approval by allowing sponsors to gain regulatory approval for their new medical countermeasures on the basis of animal studies, which model the disease in human beings. The rule stipulates that animal studies can be used to establish the effectiveness for products where the mechanisms of toxicity of the product is well understood, where the effect is established in more than one species of animal expected to be predictive for humans (in some cases one well characterized animal model could be sufficient), and the workings of the drug are sufficiently well understood to allow for the selection of an effective dose in humans (FDA, 2002).

This new animal rule pathway too has been used on several occasions already. Initially, it was mostly invoked to approve new indications for existing products. When, for example, the new procedure was first triggered on 5 February 2003, FDA approved the application of pyridostigmine bromide (PB) for prophylaxis against the lethal effects of Soman nerve agent poisoning. PB had been approved in the United States as early as 1955 – albeit for the treatment of a rare neurological disorder called myasthenia gravis (Aebbersold, 2012). The second occasion on which the new animal rule was invoked related to *Cyanokit* – an antidote for treating patients with known or suspected cyanide poisoning. *Cyanokit* had already been granted marketing authorization by the French authorities in May 1996, on the basis one prospective study and several retrospective studies in victims of smoke inhalation (Aebbersold, 2012). Following additional animal studies, the FDA gave approval to *Cyanokit* in December 2006 under the new animal rule, based primarily on a single placebo-controlled study in dogs (Aebbersold, 2012).

More recently, the animal rule has also been utilized to approve newly developed medical countermeasures. In April 2012, for example, FDA invoked the animal rule to approve *Levaquin* (levofloxacin) – an antibiotic manufactured by Johnson & Johnson intended to treat pneumonic plague. The approval was granted on the basis of tests carried out on African green monkeys (Gaffney, 2012). In December of that same year, FDA also granted approval to GlaxoSmithKline's raxibacumab – a monoclonal antibody intended to treat inhalational anthrax. In this case, one study was performed on monkeys, and three more on rabbits. At the time of writing, the biopharmaceutical company Chimerix was also developing a new smallpox antiviral (CMX001) under the animal

rule, as smallpox has been declared eradicated in human beings (Chimerix, 2013).

In Europe, moreover, the European Medicines Agency has initiated three different procedures for speeding up the availability of influenza vaccines during a pandemic. These include: 1) a 'mock-up procedure' whereby a vaccine can be authorized in advance of a pandemic on the basis of a strain that could potentially cause a pandemic; 2) an 'emergency procedure' which reduces the authorization procedure from 210 to 70 days; and 3) a 'modification' procedure whereby a 'seasonal' flu vaccine might be altered to afford protection against a pandemic strain (EMA, 2014). The introduction of such bespoke and special pathways for regulatory approval thus marks a third mechanism through which several governments are actively incentivizing the commercial development of new medical countermeasures through the introduction of extraordinary measures – in this case by drawing upon the state's power of regulation.

#### 4.4. Emergency use authorization: new pathways for using unapproved drugs

Some governments have also introduced new procedures stipulating the (emergency) conditions under which it could even be permissible to use unapproved medicines, or use medicines for purposes and indications other than those for which they were initially approved. The United States government, for example, introduced a new Emergency Use Authorization (EUA) procedure in 2004 as part of the Project BioShield Act. An EUA 'is an authorization issued by the Food and Drug Administration (FDA) for the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces, or a significant potential to affect national security' (IOM, 2010: 5).

The new policy mechanism enables the government to deploy medical countermeasures in an emergency – even if the product is not yet approved by the FDA, or has not been approved for that particular use. The determination of such an emergency can be made either by health or security authorities – specifically the Department of Health and Human Services, the Department of Homeland Security, or the Department of Defence; and the declared emergency can be a military, domestic, or public health emergency, but should be one that affects, or has a significant potential to affect, national security. The agents covered by the procedure can include a broad spectrum of chemical, biological, radiological, or nuclear agents (IOM, 2010: 27).

This new procedure has already proved useful to U.S. government officials on several occasions. It was first invoked for a medication designed to address the threat of inhalational anthrax. Subsequently the procedure has been triggered to cover antibiotic emergency kits (in 2008), and for several products during the influenza A(H1N1) pandemic of 2009 (IOM, 2010: 25). According to Susan Sherman, from the Office of General Counsel of the Department of Health and Human Services, the new procedure can greatly ease the use of pharmaceuticals during an emergency:

From a legal perspective, there are a lot of situations where [an] EUA helps get past all those requirements ... You can change the labeling. You can change the information. You can change the dosage. You can give it to populations for which [it] wasn't approved (IOM, 2010: 26).

Crucially, the role of the FDA is not completely sidestepped during the procedure; it is still up to the FDA to review the EUA request, which can be issued by the FDA Commissioner via a formal letter of authorization. The FDA will look at factors such as whether



there is a serious life-threatening illness caused by an agent, whether it is reasonable to believe that the product would be effective for its intended use, whether the known and potential benefits outweigh the risks, and whether there is no other adequate and approved medical countermeasure available (IOM, 2010:29).

Other governments are looking into introducing similar processes. In Europe, for example, the European Commission has spent much of the past decade developing its own health security framework – focussing on prevention, preparedness, and responses to threats (EC, 2009; European Commission, 2012). A new agreement on strengthening EU health security reached in 2013 also:

provides for the possibility that the Commission recognizes a situation of public health emergency for the purposes of conditional marketing authorizations for medicinal products and for derogations of the terms of a marketing authorization for a human influenza vaccine. This would allow accelerated marketing of medicinal products or vaccines in an emergency situation (EU, 2013).

Such procedures would enable – again under exceptional emergency conditions only – medical countermeasures to be deployed even without marketing approval or, in the case of Europe, via expedited approval procedures. Deploying the state's exceptional power to temporarily suspend existing regulatory frameworks during an emergency thus marks another pivotal axis in the extraordinary medical countermeasures regime that governments have been creating.

#### 4.5. Mass drug administration systems: the National Pandemic Flu Service

Governments have even developed elaborate new systems of the mass administration of medical countermeasures outside of the more established clinical settings like hospitals, doctor's surgeries, and pharmacies. Developing such new systems has been necessary to cope with the logistical challenges of rapidly distributing large quantities of medical countermeasures to the population in the event of an emergency. Perhaps the most prominent recent example of this process was the launch of the National Pandemic Flu Service (NPFS) in the United Kingdom during the 2009 influenza A(H1N1) pandemic. Faced with an unexpected surge in human H1N1 infections, which was by this time also beginning to place a heavy burden on the National Health Service (NHS), the UK authorities decided to set up a new telephone and internet-based National Pandemic Flu Service that could distribute the antiviral medication directly to members of the population. NPFS was, in the words of one report, the 'first mass application of non-clinical based triage' (Baker, 2010: 7).

In most cases, concerned citizens were able to obtain *Tamiflu* prescriptions simply by going through a quick and fairly simple online self-assessment questionnaire. Obtaining *Tamiflu* became as easy as picking up the phone or going online, connecting to the new UK Pandemic Flu website, ticking a few boxes related to a set of common flu symptoms and, where the symptoms criteria were met, note down a unique reference number to obtain *Tamiflu* from the nearest official collection point – preferably through the use of what British authorities affectionately referred to as 'flu buddies'. Not surprisingly, the system was easily open to abuse by those who wanted to create personal stockpiles of the drug. As one manager of a general medical practice noted with exasperation during the 2009 influenza A (H1N1) outbreak, 'at present, it [*Tamiflu*] might as well be given out on street corners' (Peek, 2009). Overall the service

reportedly performed 2,732,000 assessments, of which 1,800,000 resulted in antiviral authorization (Baker, 2010: 7).

Although the British system was one of the most wide-ranging and ambitious in the world, all countries which had invested in stockpiling the drug needed to develop plans for rolling out large number of treatment courses to the population in a short period of time. Different models of mass drug delivery include the use of national postal systems, relying on commercial logistics companies, or asking the military to accomplish this task. Irrespective of which model was ultimately adopted, the investment in such new models for mass pharmaceutical delivery formed an additional way for governments to signal their political commitment to this area of medical countermeasures and health security. Those new logistical systems for distributing medical countermeasures *outside* of the normal clinical settings thus mark a final pillar of the new exceptional new pharmaceutical regime that governments have recently spawned for the development of new medical countermeasures.

#### 5. Conclusion

What does this new, government-led and quite exceptional medical countermeasure regime imply for our understanding of the contemporary dynamics of pharmaceuticalization? Existing accounts of pharmaceuticalization have mostly emphasized the pivotal role of industry, and have therefore tended to accord governments a comparatively modest role. Where scholars have acknowledged the role of governments, they have tended to focus on the changing approaches taken by state regulatory agencies in approving novel pharmaceutical products (Permanand, 2006; Carpenter, 2010; Davis and Abraham, 2012). The analysis of national security policy undertaken here, however, suggests that governments are emerging as much more proactive drivers of pharmaceuticalization than this received picture suggests – necessitating an adjustment to our understanding of the underlying drivers of pharmaceuticalization.

In the name of national security, several governments are now actively incentivizing the commercial development of new pharmaceuticals through a broad array of extraordinary policy levers. New regulatory approval processes are certainly one such mechanism; but in the case of medical countermeasures they are but one of many. As we have seen, other extraordinary mechanisms introduced by governments over the past decade include the provision of earmarked public funds, the granting of extensive legal protections for pharmaceutical companies, the introduction of emergency use procedures, and the development of innovative logistical systems for mass drug administration outside of established clinical settings. Governments, in other words, are not just crucial drivers of pharmaceuticalization; they are also highly complex because their national security powers are potent, plentiful and – perhaps most critically – substantially different from the powers available to pharmaceutical companies and other actors.

This government-led medical countermeasure regime spawned in the name of national security is already accelerating, intensifying and opening up new trajectories of pharmaceuticalization in society. The regime has, for example, already enabled – through new public investment and legal protections – many novel pharmaceutical products to be developed that would otherwise not have been. Already this new medical countermeasure regime has – through the 'animal rule' and the emergency use authorization – facilitated the use of pharmaceuticals in ways that would otherwise not have been possible. And already this new pharmaceutical regime has opened up new routes for pharmaceutical consumption through the development of new logistical systems for mass drug administration outside of clinical settings – as witnessed during the 2009 H1N1 pandemic. Those are all ways in which



governments are becoming much more deeply imbricating in the pharmaceuticalization of society.

None of this is meant to imply that all those government efforts have been complete successes, and have passed without contestation. In fact, the experience of the past decade suggests that the process of medical countermeasure development has been fraught with unanticipated complexities, complications, and quite a high failure rate (Hoyt, 2012). It has simply proved much more difficult to incentivize the commercial development of new medical countermeasures than had initially been expected. For that reason the pharmaceuticalization dynamics in this sector also continue to evolve. In 2010, for example, the Department of Health and Human Services undertook a comprehensive review of the entire medical countermeasure enterprise in the United States. The review identified several adjustments that would be needed – including a Concept Acceleration Program at the National Institute of Allergy and Infectious Diseases (NIAID) – to speed up the identification of promising new medical countermeasures. It further envisioned the creation of a new ‘Strategic Investor’ office that could provide companies working in this area with detailed business advice. It also sought to invest in new surge manufacturing capacity for medical countermeasures, as well as a new Medical Countermeasure Initiative (MCMi) that would address outstanding regulatory issues around medical countermeasures at FDA. The political push for new medical countermeasures, in short, is proving to be an evolving quest. The one thing that is already becoming quite clear, however, is that in the twenty-first century our futures will not only be secured militarily – but also pharmaceutically.

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